

DRUG POLICY

Unloxcyt® (cosibelimab-ipdl)

BENEFIT APPLICATION

Benefit determinations are based on the applicable contract language in effect at the time the services were rendered. Exclusions, limitations or exceptions may apply. Benefits may vary based on contract, and individual member benefits must be verified. Wellmark determines medical necessity only if the benefit exists and no contract exclusions are applicable. This medical policy may not apply to FEP. Benefits are determined by the Federal Employee Program.

DESCRIPTION

The intent of the policy is to provide coverage consistent with product labeling, FDA guidance, standards of medical practice, evidence-based drug information, and/or published guidelines. The indications below including FDA-approved indications and compendial uses are considered covered benefits provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications

Unloxcyt (cosibelimab-ipdl) is indicated for the treatment of adults with metastatic cutaneous squamous cell carcinoma (mCSCC) or locally advanced cutaneous squamous cell carcinoma (laCSCC) who are not candidates for curative surgery or curative radiation.

All other indications are considered experimental/investigational and not medically necessary.

Limitations of Use

Coverage will not be provided for members who have experienced disease progression while on programmed death receptor-1 (PD-1) or programmed death ligand 1 (PD-L1) inhibitor therapy.

POLICY

Criteria for Initial Approval

Cutaneous Squamous Cell Carcinoma (CSCC)

Authorization of 6 months may be granted for treatment of metastatic or locally advanced CSCC when the member is not a candidate for curative surgery or radiation.

Continuation of Therapy

Cutaneous Squamous Cell Carcinoma (CSCC)

Authorization of 6 months may be granted for continued treatment in members requesting reauthorization for metastatic or locally advanced CSCC when there is no evidence of unacceptable toxicity or disease progression while on the current regimen.

Other

Unloxcyt (cosibelimab-ipdl) is considered **not medically necessary** for members who do not meet the criteria set forth above.

Members currently receiving the requested medication as samples or via the manufacturer's patient assistance program will be required to meet the criteria for initial approval. This ensures that members are treated equally regardless of their provider's ability to access medication samples.

Dosing and Administration

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

PROCEDURES AND BILLING CODES

To report provider services, use appropriate CPT* codes, Alpha Numeric (HCPCS level 2) codes, Revenue codes, and/or ICD diagnostic codes.

- J9275 – Injection, cosibelimab-ipdl, 2 mg (effective 7/1/2025)
- J9999 – Not otherwise classified, antineoplastic drugs
- J3490 – Unclassified drugs
- J3590 – Unclassified biologics

REFERENCES

- Unloxcyt [package insert]. Waltham, MA: Checkpoint Therapeutics, Inc.; December 2024.
- The NCCN Drugs & Biologics Compendium® © 2025 National Comprehensive Cancer Network, Inc. <https://www.nccn.org>. Accessed March 17, 2025.

POLICY HISTORY

Policy #: 05.05.79

Original Effective Date: September 9, 2025

Reviewed: August 2026

Revised:

Current Effective Date: September 9, 2025